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IN THE

Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari
to the Supreme Court of Vermont

BRIEF AMICUS CURIAE OF THE SENIOR CITIZENS LEAGUE IN SUPPORT OF RESPONDENT

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INTEREST OF AMICUS CURIAE[1]

The Senior Citizens League ("TSCL") is a registered d/b/a of TREA Senior Citizens League, a nonprofit, non-partisan social welfare organization, interested in the proper construction and application of the Constitution and laws of the United States. TSCL is incorporated under the laws of Colorado, and is tax-exempt under Section 501(c)(4) of the Internal Revenue Code of 1986. Headquartered in Alexandria, Virginia, TSCL is one of the nation's largest nonpartisan seniors groups, with more than 750,000 senior citizen members and supporters, engaging in education and advocacy. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned. It monitors developments in the United States with respect to the interests of senior citizens, defends those interests before government, and develops educational materials designed to explain to seniors their rights as U.S. citizens. This brief is part of TSCL's "Seniors Health Initiative," a multi-faceted program defending seniors' health rights. Although TSCL has no affiliation with the parties in this case, TSCL and its supporters may be directly impacted by this Court's resolution of the issue in this case, which concerns a claim of implied federal preemption by the petitioner that could extinguish a civil liberty long enjoyed by seniors and others.

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[1] The parties have filed blanket consents to the filing of amicus briefs. No counsel for a party authored this brief in whole or in part, and no person other than the *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission.

SUMMARY OF ARGUMENT

Petitioner Wyeth seeks a ruling from this Court that compliance with the drug labeling requirements of the Food and Drug Administration ("FDA") would impliedly preempt respondent Diana Levine's common law failure-to-warn tort claim. Wyeth's preemption claim is predicated on the mistaken view that among the powers granted to Congress is the power to protect the public health, safety and welfare, whereas, in fact, Congress enacted the Food, Drug and Cosmetics Act ("FDCA") pursuant to its power to regulate interstate commerce. By its misstatement of Congressional authority, Wyeth sidesteps the presumption against preemption of the police powers reserved to the states, as secured by the Tenth Amendment.

Additionally, Wyeth's preemption claim, if sustained, would deprive Diana Levine of her civil liberty, as secured both by the Tenth Amendment's reservation to the people of those powers not delegated to the federal government, and by Article I, Section 4, of the Vermont Constitution, which protects her right to seek a legal remedy for an injury done to her person and property. Wyeth's attempt to impute to Congress an intent to take away Ms. Levine's remedy by "due course of law" would, if sustained, violate the laws of nature, in derogation of the very nature of legislative power vested in Congress by Article I, Section 1, of the Constitution and in violation of this nation's commitment to a government of laws, not of men, as stated by Chief Justice John Marshall in Marbury v. Madison.

In its attempt to gain immunity from liability for its own negligence, Wyeth would ask this Court to disregard the benefits of state law in protecting consumers and assisting the work of the FDA. Unless supplemented by state tort law, the FDA statutory mission of drug approval and oversight sacrifices the health and safety of individual patients for the purported greatest good for the greatest number of people. Premarketing approval of drugs by the FDA is an important step in the process intended to prevent the marketing of certain potentially dangerous items, but the FDA approval and monitoring process cannot replace the comprehensive safety incentives, information disclosure, and victim compensation obtained from state liability law, as the FDA historically has acknowledged.

Moreover, even in the words of the recent report of one of its own advisory groups, the FDA's scientific expertise applied to the drug approval and oversight process is insufficient to protect the public health. According to the FDA Science and Mission at Risk Report, dated November 2007, "science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." Indeed, the Report concluded that the FDA's evaluation methods employed in the new drug approval process have not kept up with scientific advances, thus putting "American lives at risk."

Clearly, carving out a new doctrine of FDA preemption insulating drug companies from failure to warn the public adequately of risks of which the drug companies are most knowledgeable would be contrary

to both sound legal reasoning and the interests of all who depend upon the civil rights and remedies that are the bedrock of our society and government.

ARGUMENT

I. PREEMPTING RESPONDENT'S COMMON LAW TORT CLAIM WOULD DEPRIVE HER RIGHT TO A REMEDY BY "DUE COURSE OF LAW" SECURED BY THE TENTH AMENDMENT TO THE U.S. CONSTITUTION AND ARTICLE I, SECTION 4, OF THE VERMONT CONSTITUTION.

Even though the basic question before this Court is one of statutory interpretation, it cannot be addressed properly without first placing the subject matter at issue in its appropriate constitutional context. Certain preemption cases involve powers delegated by the Constitution exclusively to Congress, such as "the conduct of [the nation's] affairs with foreign sovereignties[,] [where] [o]ur system of government is such that the interest of the cities, counties and states, no less than the interest of the people of the whole nation, imperatively requires that federal power in the field affecting foreign relations be left entirely free from local interference." Hines v. Davidowitz, 312 U.S. 52, 63 (1941). Other preemption contests involve "the historic police powers of the States" that are presumed "not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress" pursuant to the exercise of a power "clear[ly]" "in the federal domain." Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 229-30 (1947).

This case — involving the health, safety, and welfare of the people of Vermont — clearly falls into the latter category, not the former. *See e.g.*, Whalen v. Roe, 429 U.S. 589, 603 n.30 (1977) ("It is well settled that the State has broad police powers in regulating the administration of drugs by the health profession."). Yet, both Petitioner Wyeth, and the Solicitor General in his amicus brief, treat the preemption issue in this case as if the federal government has plenary authority over the "public health," as it does over "foreign relations." Both place heavy reliance upon Hines for the proposition that Respondent Diana Levine's claim for compensation arising from Wyeth's failure to warn of the safety risks of its drug, Phenergan, "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of" the Food, Drug and Cosmetics Act, 21 U.S.C. Sections 301, *et seq*. *See* Brief for Petitioner ("Pet. Br."), pp. 27, 40; Brief for the United States as Amicus Curiae Supporting Petitioner ("U.S. Br."), pp. 10, 24. Further, neither pays any attention to the constitutional authority upon which the FDCA actually rests, citing the Supremacy Clause as the only constitutional provision relevant to this case,[2] as if the states retain only those power crumbs that fall from the Congressional table.

Indeed, the Solicitor General makes the sweeping and indiscriminate claim that "the Supremacy Clause (U.S. Const. Art. VI, Cl. 2) [so] subordinates state law to federal law, [that] the courts should not lightly assume that federal law is so self-negating as to authorize state law to frustrate its objectives." *See*

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[2] *See* Pet. Br., pp. viii, 2; U.S. Br., pp. v., 30.

U.S. Br., p. 30. The Solicitor General errs, however, ignoring "the starting presumption that Congress does not intend to supplant state law." *See* New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654 (1995). And Wyeth attempts to banish the presumption against preemption altogether, having relegated mention of it to a footnote near the end of its brief, fishing for support from United States v. Locke, 529 U.S. 89 (2000), wherein this Court refused to apply the presumption to a state regulation competing with a federal law "bear[ing] upon [the] national and international maritime commerce, [an] area [where] there is no beginning assumption that concurrent regulation by the State is a valid exercise of its police powers." *Id.*, 529 U.S. at 108.

Such is not the case with the issue of inadequate drug labels. Even before "the creation of the modern FDA in 1938, and its forerunner in 1908, there has been a steady stream of failure-to-warn litigation [based on state law] against drug companies." D. Vladeck, "Should Drug and Medical Device Regulation Bar State Liability Claims?" Testimony before the House Committee on Oversight and Government Reform, 110th Congress, p. 18 (May 14, 2008) ("Vladeck testimony"). And as Justice Ginsburg has documented in Riegel v. Medtronic, Inc., 552 U.S. ___, 169 L.Ed.2d 892 (2008), "state common-law claims for drug labeling and design defects [have] continued unabated despite nearly four decades of FDA regulation." *Id.*, 552 U.S. at ___, 169 L.Ed.2d at 913 (Ginsburg, J., dissenting). In view of this history, Wyeth's claim, if sustained, would be truly a radical departure from settled law.

A. Wyeth Has Failed to Overcome the Presumption Against Preemption of the Powers Reserved to the States.

Wyeth begins its argument with a citation to the Supremacy Clause in Article VI of the Constitution, stating "the Laws of the United States [shall be] the supreme Law of the Land." Pet. Br., p. 29. Conspicuously missing from its brief is any acknowledgment of the qualifying phrase that only those laws of the United States "which shall be made in Pursuance" of "[t]his Constitution" are supreme. *See* Article VI, Clause 2, U.S. Constitution. Also missing is any recognition of the Tenth Amendment's admonition that "the powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people."

By divorcing the FDCA from its constitutional moorings, Wyeth is set free to paint with a broad brush the "full purposes and objectives of Congress" (Pet. Br., p. 29) to be the protection and promotion of the "public health" (*id.*, p. 7), as if Congress had plenary, rather than enumerated, legislative power, including the power to protect the health, safety, and welfare of the people. However, "[d]espite the vast reach of the federal taxing, spending, commerce and other powers, it remains true that these powers do not add up to a plenary law making authority, and Congress may still be found to have legislated beyond the 'necessary and proper' execution of its constitutional powers." H. Linde, "Without 'Due Process'" 49 Or. L. Rev. 125, 148-49 (1970). *See, e.g.*, United States v. Morrison, 529 U.S. 598 (2000) (federal

statute purporting to establish civil remedy for victims of gender-motivated violence not authorized under either Commerce Clause or 14th Amendment).

Thus, even today, Congress remains a legislature of enumerated powers. *See* U.S. Constitution, Article I, Section 1. And the power to protect and promote the "public health" is **not** one of them. To be sure, Congress does have the power "to **provide** for the General Welfare," but that power, as the Government conceded over 70 years ago, simply "qualifies the power 'to lay and collect taxes.'" *See* United States v. Butler, 297 U.S. 1, 64 (1936). Thus, the General Welfare Clause is not a grant of power at all; rather it, along with the Common Defense Clause, limits the grant of the power to tax, denying to Congress the use of its enumerated taxing power to expand the regulatory powers of Congress. *See* Butler, 297 U.S. at 68-72.

Since Congress has no power to regulate the health, safety, and welfare of the people, as such, it can only enact laws governing such matters as a "necessary and proper" **means** to the exercise of another power enumerated in the Constitution. *See* McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316 (1819). In the case of food, drugs, and cosmetics, that enumerated power is the power "to regulate Commerce ... among the several States," as this Court ruled in Hipolite Egg Co. v. United States, 220 U.S. 45 (1911). Even Wyeth admits that the current FDA role under the FDCA is ultimately to determine whether a new drug should be approved, or an already approved drug should remain, in the stream of interstate commerce. *See, e.g.*, Pet. Br., p. 2, 5, 6, 30. *See also* 21 U.S.C. Section 331.

To be sure, part of FDA's task is to ensure that, before being distributed, a drug must meet certain safety and efficacy standards. Nonetheless, FDA's primary role is a market-regulating one, "requir[ing] premarket approval" before a drug may be introduced into interstate commerce, pursuant to a policy of "risk management," the centerpiece of which is the labeling of the drug with one eye on the health and safety of the consuming public, and the other eye on the successful marketing of the approved product. *See* Pet. Br., pp. 5-11. Indeed, FDA's mission is, first of all, "to promote the public health by **promptly and efficiently** reviewing clinical research and taking appropriate action on the **marketing** of regulated products in a **timely manner**," and secondly, to "protect the public health." *See* 21 U.S.C. Section 393(b)(1) and (2) (emphasis added).

In its brief, Wyeth is careful to camouflage its economic interests in marketing Phenergan as altruistic ones, once euphemistically stating that:

> In general, FDA regulation serves the dual objectives of protecting the public from dangerous products and promoting public health by **facilitating access to beneficial treatments.** [Pet. Br., p. 41 (emphasis added).]

Surely, FDA's approval of Phenergan, in Wyeth's eyes, not only "facilitated access to beneficial treatments," but also advanced the profitability of Wyeth. Indeed, "the right balance of warnings and instructions that promotes beneficial use of the drug while minimizing

associated risks"[3] at the same time increases the quantity of Phenergan sold. And any warning that might "'exaggerat[e] [a] risk [that] could discourage appropriate use of a beneficial drug'"[4] also would depress the market for Phenergan and lessen its profitability. Indeed, "in reality, there are few instances in which [any] company (which is trying to sell its drug) wants a *stronger* label than the FDA...." Kessler, D. and David Vladeck, "A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims," 96 Geo.L.J. 461, 479 (2008) (hereafter "Kessler-Vladeck Article").

The Solicitor General, like Wyeth, is equally coy about Wyeth's economic interests in FDA labeling decisions. In his description of the FDA protective and promotional roles, he fails to acknowledge that the FDA's balancing of health risks and benefits impacts on Wyeth's balance sheet as well. For example, while he acknowledges that "[o]verwarning can ... deter beneficial uses of a drug," he does not go on to explain that such deterrence also can have an adverse impact on a drug's profitability. *See* U.S. Br., p. 19. As Aaron Kessleheim of the Harvard Medical School recently testified, "[m]anufacturers have a strong financial incentive to promote their drugs' effectiveness and increase sales of their products...." A. Kesselheim, M.D., J.D., "Should Drug and Medical Device Regulation Bar State Liability Claims?" Testimony before the House Committee on Oversight and

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[3] Pet. Br., p. 42.

[4] *Id.*

Government Reform, 110th Congress (May 14, 2008) p. 2.

The point here is not to fault Wyeth's efforts to make a profit, but to bring to the foreground that Wyeth's economic interests can influence the FDA's labeling/warning decision-making process and also drive its effort to bar access to the courthouse door to Ms. Levine. While Wyeth may obscure its economic interests, it cannot bury the fact that those interests played a key role in both the initial and ongoing FDA assessments of risk and efficacy, as well as in the ultimate labeling requirement of Phenergan. After all, the FDA's role was not an adversarial one. Rather, it was managerial — one in which the manufacturer and the FDA worked together to craft a mutually satisfactory label for the marketing of the drug. *See* Pet. Br., pp. 11-16. Thus, the label which emerged from the negotiations between Wyeth and the FDA was a label that satisfied the marketing interests of Wyeth together with the public health interests of the FDA. *See* Pet. Br., pp. 17-18.

This administrative process, whereby the regulated manufacturer jointly with the FDA agrees to the adequacy of a warning on its marketed product, gives rise to the real concern that, while the FDA is "ostensibly regulating [in] the 'public interest,' [that interest] is equated more and more with the interest of those being regulated." *See* B. Schwarz, Administrative Law § 1.11, p. 26 (2d Ed. Little Brown: 1984). FDA decisions are often "made by unelected and unaccountable agency officials — many of whom worked for drug and device companies before their government service and have returned or will return

via the revolving door to represent the same companies." Vladeck testimony, pp. 2-3. In any event, the managerial decision mutually agreed to by the FDA and Wyeth did not meet the **individual** safety and efficacy interests of Diana Levine. Nor did it meet her remedial interests to be compensated for an injury suffered as a consequence of the inadequacy of the FDA-approved label. That should come as no surprise, for completely missing from the FDCA is any remedial provision administering compensation for injuries that occur because the FDA erred in approving a label that did not adequately warn Ms. Levine and her physician of the risks of intravenous application of Phenergan by IV push. Indeed, "when the 1938 Act was being debated, Congress was told that the bill did not need to create a federal claim for damages because state law already permitted such actions to be brought." Vladeck testimony, p. 16. Seventy years later, there still is no such federal cause of action or other remedial measure.

As noted above, Wyeth and the Solicitor General rely heavily upon Hines (312 U.S. at 67), for their contention that Vermont tort law is preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Pet. Br., pp. 27, 40, 41; U.S. Br., pp. 10, 24. However, the "purposes and objectives" of the FDCA do not "fully" protect the public health, in that the statute does not include compensation for injuries caused by faulty warning labels approved by the FDA.[5] This is due, in part, to the limited

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[5] When federal statutes nullify existing state damage claims "they do so in unmistakable terms and generally provide a federal

constitutional authority of Congress which must act only "within the sphere of delegated power," which, in turn, limits the preemptive effect of the federal enactment on state law. *See* Hines, 312 U.S. at 68 n.20.

The sphere of power delegated to Congress, and reflected in the FDCA, is interstate commerce, **not** the public health and safety. *See, e.g.*, 21 U.S.C. Section 331. Therefore, as a matter of constitutional law, Congress' concern for public health and safety is only a "necessary and proper" means to facilitate and protect the commercial interests of the nation, "preventing trade" in mislabeled, dangerous, and inefficacious drugs "between the states by denying to them the facilities of interstate commerce." *See* Hipolite Egg, 220 U.S. at 58. And, as was true of Congress' prohibition of the interstate transportation of lottery tickets, the FDCA's interdiction of such drugs that do not meet FDA's minimum standards of safety and efficacy is designed to "supplement,"[6] not to override, the state's common law tort system providing for compensation for persons injured by the wrongful conduct of another. For nearly 100 years, the two have co-existed, state tort law protected by the presumption against preemption. *See* Riegel v. Medtronic, 552 U.S. ___, ___, 169 L.Ed.2d 892, 913-14 (2008) and cases cited (Ginsburg, J., dissenting). Wyeth and the Solicitor General have not rebutted this presumption.

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remedy in lieu of displaced state remedies." Vladeck testimony, p. 9.

[6] *See* Champion v. Ames, 188 U.S. 321, 357 (1903).

B. Diana Levine's Exercise of Her Individual Right to a Remedy for Wyeth's Wrongful Action Is a Power Reserved to the People.

Not only does the presumption against preemption protect the "reserved" powers of the states to protect the health, safety, and welfare of their people, it also protects those powers that, by nature, belong to the people, as provided in the Tenth Amendment. As Joseph Story observed, those powers not invested in either the federal or state governments are "retained by the people, as part of their residuary sovereignty." 2 J. Story, Commentaries on the Constitution, Section 1907, p. 652 (5th ed., Little Brown: 1891). According to the nation's charter, it is the sovereign right of the people to constitute and to reconstitute their government so that their God-given rights to life, liberty, and the pursuit of happiness are secured. To that end, the people of each State and the people of the United States consented to their respective governments, distributing between them those powers that they saw fit, and prohibiting them from the exercise of powers that they believed unfit for a freedom-loving people.

Admitted in 1791 as the fourteenth state in the union, the people of Vermont did not delegate, nor had the people of the original 13 states so delegated, to the federal government any power to enact a general system of tort law. Rather, that was a power reserved to the State, just as it had been reserved to the original 13. Additionally, in 1786 before Vermont was admitted to the union, and again in 1793, the people of Vermont retained the right "to find a certain remedy, by having recourse to the laws, for all injuries or

wrongs which he may receive in his person, property or character." Vermont Constitution, Chapter 1, Article 4. *See* http://vermont-archives.org/govhistory/constitut/con93.htm. In reserving this right to the people, the people of Vermont followed in the footsteps of the people of Delaware. *See* Delaware Declaration of Rights, Section 12. *See also* Sources of Our Liberties, p. 339 (Rev. ed., R. Perry and J. Cooper eds.; ABA Foundation: 1978). And as former Oregon Supreme Court Justice Hans Linde has written, the Delaware Declaration spawned other comparable provisions, including Article I, Section 10 of the Oregon Constitution, all of which were:

> directed against the denial of a legal remedy to one who has a claim, arising from "injury done him in his person, property, or reputation".... For such a recognized legal injury, "every man shall have remedy by due course of law." [H. Linde, "Without 'Due Process,'" 49 Ore. L. Rev. 125, 136 (1970).]

This right to a remedy for wrong done is rooted in the "law of nature," namely, that every person has, by nature, "a particular right to seek reparation from" another who has damaged him in his person or property. J. Locke, The Second Treatise of Government, Chapter II. 10. Further, by that same law of nature, a civil magistrate cannot:

> by his own authority remit the satisfaction due to any private man for the damage he has received. That he who has suffered the damage has a right to demand in his own name, and he alone can remit; the damnified person has this power of

> appropriating to himself the goods or service of the offender by right of self-preservation. [*Id.*, Ch. II. 11.]

Aware of these Lockean principles, and considering themselves to have been in a "state of nature" in 1777-78, the people of Vermont "form[ed] a government best suited to secure their property, well being and happiness." *See* P. Gillies, "Not Quite a State of Nature: Derivations of Early Vermont Law," 23 Vt. L. Rev. 99, 99 n.1, 129-31 (Fall: 1998). Unlike her predecessor states, "Vermont had never been a crown colony, and it had never been recognized as a separate governmental entity by any state." Sources of Our Liberties, *supra*, p. 358. Exercising their "prerogatives of sovereignty," the people of Vermont constituted their government to enable themselves "to enjoy their natural rights, and the other blessings which the Author of existence has bestowed upon man." *Id.* at 362.

Two hundred and ten years later, the Vermont Supreme Court upheld one of these natural rights, ruling that any statute or rule, "must give way ... if its application would deprive [a] plaintiff ... of his constitutional right to a remedy under Chapter I, Article 4 of the Vermont Constitution." Lillicrap v. Martin, 156 Vt. 165, 177-78, 591 A.2d 41, 48 (1989). Thus, if this Court were to construe the FDCA to preempt Diana Levine's common law tort claim against Wyeth, it would be denying Vermont's constitutional guarantee of providing Diana Levine the opportunity to seek individual redress for an alleged legal wrong committed by Wyeth, Congress having provided no comparable remedy for such wrong. *See*

Sienkiewycz v. Dressell, 151 Vt. 421, 424-25, 561 A.2d 415, 424-25 (1989). Instead, this Court will have ruled that Congress intended to extinguish Diana Levine's individual tort claim to forward its purpose of having the public health protected by "having an expert agency balance drug risks and benefits,"[7] even at the price of Ms. Levine's amputated arm.

Such imputation of Congressional intent would violate the laws of nature upon which these United States were founded, in derogation of the very nature of legislative power vested in Congress by Article I, Section 1:

> [T]he law of nature stands as an eternal rule to all men, legislatures as well as others. The rules that they make for other men's actions must ... be conformable to the law of nature — i.e. the will of God, of which that is a declaration — and the fundamental law of nature being the preservation of mankind, no human sanction can be good, or valid against it. [J. Locke, 2d Treatise, Ch. XI. 135.]

Indeed, such a preemption decision would undercut one of the "chief ends" of civil government, namely, to counter weigh the ability of the powerful to escape their duty to make reparations for wrongs done to those less powerful. *See* J. Locke, 2d Treatise, Ch. IX. 123-131.

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[7] *See* Pet. Br., p. 24.

C. Depriving Diana Levine of her Common Law Right to a Remedy for Injury Caused by Wyeth Is Contrary to the Rule of Law.

Even the most careful search of the legislative powers vested in Congress by the Constitution reveals no enumerated power to deprive a person who has a common law right of "a legal remedy by suit or action at law, whenever that right is invaded."[8] As Chief Justice John Marshall stated in Marbury v. Madison, 5 U.S. (1 Cranch) 137 (1803):

> The very essence of civil liberty certainly consists in the right of **every individual** to claim the **protection of the laws**, whenever he receives an injury. One of the **first duties of government is to afford that protection**. [*Id.*, 5 U.S. at 163 (emphasis added).]

There is no question in this case that, according to the common law of Vermont, Diana Levine had a legal right not to lose her arm and her livelihood as a consequence of Wyeth's "fail[ure] to provide adequate warnings of the known dangers of injecting Phenergan directly into [her] vein." *See* Levine v. Wyeth, 944 A.2d 179, 182 (Vt. 2006). There is also no question that, if this common law right were preempted by the FDA's approval of the Phenergan label, then Diana Levine would have no remedy whatsoever for the legal wrong done by Wyeth to her person, her liberty, and her property, for she would be left with no legal recourse to right this egregious wrong.

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[8] *See* III W. Blackstone, Commentaries on the Laws of England, p. 23 (U. Chi. Facsimile ed.: 1768).

In his Commentaries on the Laws of England, Sir William Blackstone observed that "it is a settled and invariable principle in the laws of England, that **every right**, when withheld, **must have a remedy, and every injury its proper redress.**" III. W. Blackstone's Commentaries, p. 109 (emphasis added). And it was in response to this observation that Chief Justice Marshall wrote his now famous paean about the legal system of the newly formed United States of America:

> The government of the United States has been emphatically termed a government of laws, and not of men. It will certainly **cease** to deserve this high appellation, **if the laws furnish no remedy for the violation of a vested legal right.** [Marbury, 5 U.S. at 163 (emphasis added).]

Should this Court find that Congress, by enacting the Food, Drug and Cosmetic Act, has preempted the application of Vermont's common law of torts to the failure of Wyeth properly to warn Diana Levine and her physician of the dangers of the "IV-push" method of injecting Phenergan directly into her vein, then it would simultaneously be signing: (a) the death warrant to a government providing for individual redress according to the rule of law administered by a jury of one's peers; and (b) the birth certificate to a government providing for the collectivist good, according to the pragmatic opinion of scientists administered by unelected bureaucrats in Washington, D.C. *See* Pet. Br., pp. 2-4, 23, 24, 28-29, 40-41, 46 and 50-51.

This Court's preemption doctrine ought not be so construed and applied. To do so would transform a legal transgression into a "mere political act," the wrongful exercise of which would leave the "injured individual" with "no remedy." *See* Marbury, 5 U.S. at 164.

II. IN ITS DRIVE TO GAIN IMMUNITY FROM LIABILITY ARISING FROM ITS NEGLIGENCE, PETITIONER DISREGARDS THE BENEFITS OF THE STATE TORT LIABILITY SYSTEM IN PROTECTING CONSUMERS AND ASSISTING THE WORK OF THE FDA.

Petitioner asserts that the state tort system presents a "direct and positive conflict" with the FDA's role in regulating drug labeling. Pet. Br., pp. 51-54. However, rather than conflicting with the FDA labeling process, the state tort liability system for decades has complemented and assisted the FDA's role under FDCA. "For most of its seventy-seven year history, the Food and Drug Administration (FDA) has regulated the drugs sold in the United States without any significant interaction with the world of state-law damages litigation.... The agency's practice of non-participation in litigation was in keeping with the FDA's view that its regulatory efforts could comfortably coexist with state-law damage claims by consumers injured by drugs." Kessler-Vladeck Article, pp. 462-463.

This mutually-reinforcing relationship was described during the May 14, 2008 hearings held by the House Committee on Oversight and Government

Reform on "Should Drug and Medical Device Regulation Bar State Liability Claims?"[9]

At those hearings, former FDA Commissioner David A. Kessler, who served under both President George H.W. Bush and President William J. Clinton, cited in his written testimony a statement from the agency's chief counsel made in 1996 summarizing the FDA's position at that time, that Kessler said was applicable equally to both devices and drugs, and which is contrary to the position advanced by the government in this case[10]:

> FDA's view is that **FDA product approval** and **state tort liability** usually operate **independently**, each providing a significant yet distinct layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. **Preemption of all such claims would result in the loss of a significant layer of consumer protection leaving consumers without a remedy** caused by defective medical devices. [D. Kessler, "Should Drug and Medical Device Regulation Bar State Liability Claims?" Testimony before the House Committee on

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[9] Copies of the witnesses' testimony, Chairman Waxman's Opening Statement, and a "Preliminary Hearing Transcript" are available at: http://oversight.house.gov/story.asp?ID=1943.

[10] *See* U.S. Br., pp. 10, 17-21.

Oversight and Government Reform, 110th Congress (May 14, 2008), p. 2 (emphasis added) ("Kessler testimony").]

Indeed, former Commissioner Kessler explained that it is "the manufacturers, not the Agency, that are in a far better position to know when a new risk emerges from a drug ... [a]nd it is the manufacturer that has the ability to make swift changes to a drug ... warning or product features. Doing away with the incentives to act responsibly and expeditiously to correct potential risks, incentives that are the result of state [tort] liability cases, would ... jeopardize the public's health." Kessler testimony, p. 8.

Georgetown University Law Center Professor of Law David C. Vladeck reinforced this view by explaining that "[s]tate liability litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process, and this 'feedback loop' enables the agency to better do its job." Vladeck testimony, p. 24. Vladeck observed that "[t]ime and again, failure-to-warn litigation has brought to light information that would not otherwise be available to FDA, to doctors, to other health care providers, and to consumers. And failure-to-warn litigation has often preceded and clearly influenced FDA decisions to modify labeling, and, at times, to withdraw drugs from the market." *Id.*, pp. 24-25.

In his Opening Statement to the May 2008 Oversight Committee hearings on FDA preemption, Committee Chairman Waxman explained how some profit-making pharmaceutical firms have operated, and how the public safety would be worsened by

federal preemption: "Some drug and device companies have hidden and manipulated important safety data ... failed to report serious adverse events ... [and] failed to disclose known defects. If manufacturers face no liability, all the financial incentives will point them in the wrong direction, and ... abusive practices will multiply." At that point "even if a company withholds information about potentially fatal defects from physicians, patients, or the FDA, it is still immune from liability...." H. Waxman, Chairman, Waxman Opening Statement, "Should Drug and Medical Device Regulation Bar State Liability Claims?" Hearing, House Committee on Oversight and Government Reform, 110th Congress (May 14, 2008), pp. 1-2.

As contrasted with the current system where federal regulation and state tort liability exist side by side, Chairman Waxman described the type of preemption claims made by the pharmaceutical industry as a "radical legal doctrine" under which "one of the most powerful incentives for safety — the threat of liability — would vanish." *Id.*, p. 1.

It is undisputed that the FDA, until relatively recently, espoused the view "that state tort law [does] not interfere with federal regulation" in the area of the FDA's drug labeling oversight, and that it was only in 2006, in finalizing a new regulation concerning a "Highlights" section on drug labels, that the FDA officially espoused a diametrically different view. Respondent's Brief in Opposition, pp. 8-9. And no persuasive reason has been offered for the FDA's about-face. In fact, in view of the FDA's own admitted concerns about its ability to keep abreast of scientific developments (*see* Section III, *infra*), the timing of the

FDA pronouncement could hardly be worse. Certainly, the argument against federal preemption with respect to pharmaceutical warnings neither advocates nor promotes agency inattention or inaction. Quite to the contrary, the FDA is integrally involved in approving every drug for marketing, and the FDA — by regulation — has a voice in the form and content of the drug label, as well.

But that is not to say that the FDA initiates label changes, or that it must approve any and all label changes before they are made. Even if the petitioner's argument that it could not have made a change to Phenergan's label without FDA approval (Pet. Br., pp. 34-40) were true[11], it is clear from the decision below, as well as from a reading of the relevant FDA regulations, that a drug manufacturer has the prerogative to initiate changes to a drug label's warning in the interest of public safety, and there is no evidence that, had it unilaterally initiated or made such a change with respect to Phenergan, it would have been subject to any adverse regulatory action as to liability for unauthorized distribution or misbranding. *See* Wyeth v. Levine, 944 A.2d at 185-86, 188-89; Resp. Br. 31-45. *See also* 21 C.F.R. § 314.70(c); Kessler-Vladeck Article, pp. 479-80.

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[11] This contention is certainly not uncontested. *See* Vladeck testimony, pp. 19-21.

III. THE FDA'S SCIENTIFIC EXPERTISE APPLIED TO THE DRUG APPROVAL AND OVERSIGHT PROCESS ALONE IS INSUFFICIENT TO PROTECT THE PUBLIC HEALTH.

Underlying the claim to FDA preemption is the assumption that the FDA drug approval process is scientifically sound, unbiased, and comprehensive — that it alone is sufficient to ensure a drug's safety and effectiveness. That assumption is false. According to a recent report by one of its own Advisory Boards, FDA scientific expertise is inadequate, placing the nation's health at risk. *See* FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology of the FDA's Science Board (November 2007) (hereinafter "FDA Science Report"), at 2-6.

On March 31, 2006, the FDA Commissioner requested his Advisory Board — the **Science Board** — to form a Subcommittee to conduct a broad review of FDA scientific capacities, processes and infrastructure which support FDA's core regulatory functions of pre-market review, product quality oversight, and post-market safety surveillance. The Science Board created a **Science and Technology Subcommittee**, instructing it to: (1) uncover "any important gaps in current scientific capacities"; (2) identify "areas of science" where the FDA should maintain, strengthen or refocus its efforts; (3) explore "opportunities ... to enhance overall effectiveness, [including] priority setting"; and (4) identify opportunities for "collaboration" to enhance FDA's scientific and technological capacities. FDA Notice,

"Request for Comments on the Science and Technology Report ...," 73 *Fed. Reg.* 869, at 870 (Jan. 4, 2008).

This charge culminated in the FDA Science Report of November 2007, and the Subcommittee's conclusion that "science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." FDA Science Report, at 2. Indeed, the Report concluded that the FDA's "evaluation methods" employed in the new drug approval process have not kept up with "scientific advances," thus putting "American lives at risk." *Id.*[12]

The 2007 FDA Science Report also revealed that the FDA clearly overstated its scientific prowess in claiming that its scientific evaluations are authoritative, the 2007 Report having concluded, for example, (i) that "not only can the Agency not lead, it cannot even keep up with the advances in science" (FDA Science Report, at 3), (ii) that the "FDA cannot fulfill its surveillance mission because of inadequate staff and IT resources to implement cutting-edge

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[12] The FDA Subcommittee concluded that the FDA is in a precarious position based, *inter alia*, on the following specific findings: the FDA suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities (FDA Science Report, at 2); substantial weaknesses across the FDA (*id.*, at 3); the FDA can neither keep up with the advances of science nor fulfill its surveillance mission because of inadequate staff and IT resources (*id.*, at 3-4); and the FDA Information Technology infrastructure is obsolete, unstable, and lacks controls to execute effective disaster recovery protocols that ensure continuity of operations when systems are compromised (*id.*, at 5).

approaches to modeling, risk assessment and data analysis" (*id.* at 4), and (iii) that "scientific capabilities and capacity at the FDA overall are unevenly meeting current requirements, have areas of serious deficiencies and are not positioned to meet future needs." *Id.* at 20.

In sum, the FDA Science Report documents both that "the Agency ... is not positioned to meet current or emerging regulatory responsibilities" and that the FDA knows its processes are flawed. *Id.* at 2. However, those facts have not prompted the FDA to reexamine the foundation for its new preemption policy issued just the year prior to the FDA Science Report.

In justifying its claim for preemption, the FDA described itself as "the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading." *See* "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products," 71 *Fed. Reg.* 3921, 3934 (Jan. 24, 2006). Dismissing the view of "many courts" that "supplementary state law serves as an appropriate source of supplementary safety regulation for drugs by encouraging or requiring manufacturers to disseminate risk information beyond that required by FDA," the FDA opined that "additional requirements for the disclosure of risk information are not necessarily more protective of patients." *Id.* at 3934-3935. Claiming that state law actions "threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating

and regulating drugs," the FDA argued that such actions "encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public — the central role of the FDA — sometimes on behalf of a single individual or group of individuals." *Id.* at 3935. Particularly in light of the FDA's own deficiencies revealed in the FDA Science Report, the FDA wrongly has belittled the role of expert opinion in a typical state common law tort action, by its assertion of "second-guessing" by a "lay" judge or jury.

Indeed, the FDA Science Board's low appraisal of the quality of FDA science confirms that a grant of immunity to drug manufacturers from individual tort claims based upon state law would clearly be unjustified. Whether the FDA's inadequacies are based upon a lack of adequate financial resources, or upon lack of confidence in the quality of FDA scientific experts, it would be inconsistent with the FDCA and long-standing FDA policy, as well as misguided in consideration of public safety, to establish a policy of federal preemption, precluding individual law suits based upon the FDA's "scientific expertise," in the face of the FDA's own Science Report conceding, *inter alia*, that "[t]he development of medical products based on 'new science' cannot be adequately regulated by the FDA." FDA Science Report, at 49.

In 2006, the Institute of Medicine ("IOM") also reported that the FDA "lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future." Vladeck testimony, pp. 23-24. FDA's Office of Drug Safety, responsible for monitoring adverse events

associated with the 3,000 prescription drugs (and 11,000 drugs altogether) on the market, has about 100 professional employees. *Id.* *See also* FDA Science Report, at 30-33 (recommending that FDA should immediately implement the IOM recommendations for improving drug safety).

Former FDA Commissioner Kessler, in his May 2008 Oversight Committee testimony, summarized cogently some of the FDA's limitations regarding its monitoring of drug safety and the critical role state tort law plays in promoting public safety:

> [T]here are real limits imposed by the limited resources the agency has available. The case for preemption must be examined in light of a clear-eyed appraisal of the FDA's ability to assure the safety of the drugs being marketed in the United States ... and many worry that the FDA is not adequately monitoring the safety of drugs once they are on the market. The FDA has long been hamstrung by resource limitations.... [T]he tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients, and the FDA about newly emerging risks. My greatest concern with preemption is that it would, I believe, dramatically reduce the incentives for manufacturers to act quickly and responsibly to detect, analyze, investigate, and take action on potentially serious and life threatening adverse reactions once a drug is on the market. [Kessler Testimony, pp. 6-7.]

Preemption of state tort liability in failure-to-warn cases against negligent drug manufacturers could be expected to do enormous damage to the health of all Americans, particularly in light of the scientific deficiencies of the FDA, as documented by its own Science Board.

CONCLUSION

For the foregoing reasons, the decision of the Supreme Court of Vermont should be affirmed.

Respectfully Submitted,

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